

WHAT IS CLAIMED IS:

1. Amorphous celecoxib.
2. A celecoxib drug substance wherein the celecoxib is present, in at least a detectable amount, as amorphous celecoxib.
- 5 3. The drug substance of Claim 2 wherein the amorphous celecoxib is present in an amount of about 10% to about 100% by weight of the celecoxib.
4. The drug substance of Claim 2 that comprises substantially phase pure amorphous celecoxib.
5. A celecoxib-crystallization inhibitor composite comprising particles of
10 amorphous celecoxib in intimate association with one or more crystallization inhibitor(s) in an amount effective to reduce transformation of amorphous celecoxib to crystalline celecoxib.
6. The composite of Claim 5 wherein the crystallization inhibitor is a polymer.
7. The composite of Claim 6 wherein the polymer is selected from
15 polyvinylpyrrolidone and hydroxypropylmethylcellulose.
8. The composite of Claim 6 wherein the polymer is polyvinylpyrrolidone.
9. The composite of Claim 5 wherein the crystallization inhibitor(s) are present in a total amount of about 10% to about 80% by weight of the composite.
10. A celecoxib-crystallization inhibitor composite comprising particles of a
20 celecoxib drug substance of Claim 2 in intimate association with one or more crystallization inhibitor(s) in an amount effective to reduce transformation of amorphous celecoxib to crystalline celecoxib.
11. The composite of Claim 10 wherein the crystallization inhibitor is a polymer.
12. The composite of Claim 11 wherein the polymer is selected from
25 polyvinylpyrrolidone and hydroxypropylmethylcellulose.
13. The composite of Claim 11 wherein the polymer is polyvinylpyrrolidone.
14. The composite of Claim 10 wherein the crystallization inhibitor(s) are present in a total amount of about 10% to about 80% by weight of the composite.

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15. A pharmaceutical composition comprising amorphous celecoxib in a total celecoxib dosage amount of about 10 mg to about 1000 mg, and one or more pharmaceutically acceptable excipients.
 - 5 16. A pharmaceutical composition comprising a celecoxib drug substance of Claim 2 in a total celecoxib dosage amount of about 10 mg to about 1000 mg, and one or more pharmaceutically acceptable excipients.
 17. A pharmaceutical composition comprising a celecoxib-crystallization inhibitor composite of Claim 5, in a total celecoxib dosage amount of about 10 mg to about 1000 mg, and one or more pharmaceutically acceptable excipients
 - 10 18. A pharmaceutical composition comprising a celecoxib-crystallization inhibitor composite of Claim 10, in a total celecoxib dosage amount of about 10 mg to about 1000 mg, and one or more pharmaceutically acceptable excipients.
 19. A process for preparing a celecoxib drug substance, the process comprising
 - (a) melting celecoxib;
 - 15 (b) rapidly cooling the resulting melted celecoxib to form a celecoxib drug substance wherein the celecoxib is present, in at least a detectable amount, in amorphous form; and optionally
 - (c) grinding the celecoxib drug substance to form a celecoxib drug substance powder.
 - 20 20. A process for preparing a celecoxib-crystallization inhibitor composite, the process comprising
 - (a) dissolving celecoxib and one or more crystallization inhibitors in a solvent liquid to form a solution;
 - (b) drying the solution to form a celecoxib-crystallization inhibitor composite
 - 25 wherein the celecoxib is present, at least in a detectable amount, in amorphous form; and optionally
 - (c) grinding the celecoxib drug substance to form a celecoxib-crystallization inhibitor composite powder.
 21. The process of Claim 20 wherein drying step (b) is performed by spray drying.
 - 30 22. The process of Claim 20 wherein the solvent liquid comprises isopropanol.



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23. A process for preparing a pharmaceutical composition, the process comprising
- (a) blending amorphous celecoxib, or a celecoxib drug substance wherein the celecoxib is present, in at least a detectable amount, as amorphous celecoxib, with one or more excipients to form a blend; and
- 5 (b) tableting or encapsulating the blend to form celecoxib tablets or capsules respectively.
24. The process of Claim 23, further comprising granulating the blend to form a granulate prior to tableting or encapsulating.
25. The process of Claim 24 wherein granulating is performed by wet granulation to
- 10 form a wet granulate, and wherein the wet granulate is dried prior to tableting or encapsulating.
26. A process for preparing a pharmaceutical composition, the process comprising
- (a) blending a celecoxib-crystallization inhibitor composite of Claim 5 with one or more excipients to form a blend; and
- 15 (b) tableting or encapsulating the blend to form celecoxib tablets or capsules respectively.
27. The process of Claim 26, further comprising granulating the blend to form a granulate prior to tableting or encapsulating.
28. The process of Claim 27 wherein granulating is performed by wet granulation to
- 20 form a wet granulate, and wherein the wet granulate is dried prior to tableting or encapsulating.
29. A process for preparing a pharmaceutical composition, the process comprising
- (a) blending a celecoxib-crystallization inhibitor composite of Claim 10 with one or more excipients to form a blend; and
- 25 (b) tableting or encapsulating the blend to form celecoxib tablets or capsules respectively.
30. The process of Claim 29, further comprising granulating the blend to form a granulate prior to tableting or encapsulating.

31. The process of Claim 30 wherein granulating is performed by wet granulation to form a wet granulate, and wherein the wet granulate is dried prior to tableting or encapsulating.
- 5 32. A method of treating a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated, comprising orally administering one or more dose units of a composition of Claim 15 once or twice a day.
- 10 33. A method of treating a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated, comprising orally administering one or more dose units of a composition of Claim 16 once or twice a day.
- 15 34. A method of treating a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated, comprising orally administering one or more dose units of a composition of Claim 17 once or twice a day.
35. A method of treating a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated, comprising orally administering one or more dose units of a composition of Claim 18 once or twice a day.